

Rec'd PCT/PTO 23 FEB 2005

PATENT COOPERATION TREATY

PCT

REC. 29 OCT 2004

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

WIPO

PCT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 38-21(15414)		FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US03/26510	International filing date (day/month/year) 26 August 2003 (26.08.2003)	Priority date (day/month/year) 29 August 2002 (29.08.2002)	
International Patent Classification (IPC) or national classification and IPC IPC(7): C12N 15/32, 15/82, 5/04; A01H 5/00, 5/10, 1/00; C07K 14/325 and US Cl.: 535/23.71, 102; 800/302, 279, 265			
Applicant MONSANTO TECHNOLOGY, LLC			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>3</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of ___ sheets.</p>			
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>			
Date of submission of the demand 06 February 2004 (06.02.2004)		Date of completion of this report 20 October 2004 (20.10.2004)	
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230		Authorized officer Anne R. Kubelik <i>A. Roberto for</i> Telephone No. (571) 272-1600	

Form PCT/IPEA/409 (cover sheet)(July 1998)

I. Basis of the report**1. With regard to the elements of the international application:***

- ☒ the international application as originally filed.
- ☒ the description:
pages 1-55 as originally filed
pages NONE filed with the demand
pages NONE filed with the letter of _____.
- ☒ the claims:
pages 56-60 as originally filed
pages NONE as amended (together with any statement) under Article 19
pages NONE filed with the demand
pages NONE filed with the letter of _____.
- ☐ the drawings:
pages NONE as originally filed
pages NONE filed with the demand
pages NONE filed with the letter of _____.
- ☒ the sequence listing part of the description:
pages 1-75 as originally filed
pages NONE filed with the demand
pages NONE filed with the letter of _____.

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☒ contained in the international application in printed form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/~~fig~~ NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. STATEMENT**

Novelty (N)	Claims <u>1-6, 8-13 and 15-22</u>	YES
	Claims <u>7 and 14</u>	NO
Inventive Step (IS)	Claims <u>1-6, 8-13 and 15-22</u>	YES
	Claims <u>7 and 14</u>	NO
Industrial Applicability (IA)	Claims <u>1-22</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Claims 1-22 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

Claims 1-6, 8-14 and 15-22 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a nucleic acid of bases 7-1803 of SEQ ID NO:3, bases 2650-4446 of SEQ ID NO:5, bases 3047-4844 of SEQ ID NO:8, bases 1247-3043 of SEQ ID NO:11 or bases 1658-3454 of SEQ ID NO:13.

Claims 7 and 14 lack novelty under PCT Article 33(2) as being anticipated by DONOVAN et al (1994, US Patent 5,322,687). Donovan et al teach a nucleic acid encoding amino acids 2-600 of SEQ ID NO:2 and amino acids 3-601 of SEQ ID NOs: 4, 7, 10, 12 and 14 (see SEQ ID NO:3); the protein they call cryET4 is identical to the instant cry1Bb. Donovan et al also teach a method of producing a transgenic plant resistant to lepidopteran infestation by transformation with the nucleic acid (column 11, lines 1-12).

In a response filed 16 August 2004, Applicant attempted to cancel claim 7 and amend claim 14. However, this amendment did not follow Rule 66.89a), which states: "the applicant shall be required to submit a replacement sheet for every sheet of the international application which, on account of an amendment, differs from the sheet previously filed." The amendments were not sent in the form of replacement sheets, and thus could not be entered.

In that response Applicant's arguments are addressed relative to the amendments in claim 14; because those amendments were not entered, applicant's arguments do not apply.